STATE PROCUREMENT OFFICE

NOTICE OF REQUEST FOR EXEMPTION FROM HRS CHAPTER 103D

'13 OCT -2 P1:12

STATE PROCUREMENT OFFICE
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: DOH/FHSD/Children with Special Health Needs Branch
Name of Requesting Department

Pursuant to HRS § 103D-102(b)(4) and HAR chapter 3-120, the Department requests a procurement exemption for the following:

1. Describe the goods, services or construction:
Please see attached document

2. Vendor/Contractor/Service Provider:	Cincinnati Children's Hospital Medical Center Molecular Genetics Laboratory	3. Amount of Request: $ 2,288
4. Term of Contract From: 9/1/2013	To: 3/31/2014	5. Prior SPO-007, Procurement Exemption (PE): N/A

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:
Please see attached document

7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/service provider:

This vendor was selected based on (1) a previously established professional relationship between the Hawaii Newborn Metabolic Screening Program, the Oregon State Public Health Laboratory (where Hawaii's newborn bloodspots undergo newborn screening analysis and are stored), and the CCHMC laboratory; and (2) CCHMC's offer to complete the VLCADD testing at cost for this quality improvement project. Discussions between the Hawaii Department of Health Genomics Program, the Hawaii Newborn Metabolic Screening Program, the Oregon State Public Health Laboratory, and the CCHMC laboratory have been on-going for months to identify logistical and financial considerations. The CCHMC laboratory has agreed to perform the testing at cost. The relative ease of logistics and beneficial financial considerations were instrumental in choosing CCHMC as the vendor for this project.

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8. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required).
*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	e-mail address
Gordon Takaki	Family Health Div.	733-8365	Gordon.Takaki@doh.hawaii.gov

All requirements/approvals and internal controls for this expenditure is the responsibility of the department. I certify that the information provided above is, to the best of my knowledge, true and correct.

Department Head Signature

Date 10/1/13

For Chief Procurement Officer Use Only

Date Notice Posted: 10-2-13

Inquiries about this request shall be directed to the contact named in No. 8. Submit written objection to this notice to issue an exempt contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

Department has withdrawn the request and will utilize the appropriate method of procurement. If there are any questions, please contact Bonnie Kahakui at 587-4702, or bonnie.a.kahakui@hawaii.gov.

☐ Approved ☐ Disapproved ☑ No Action Required

Chief Procurement Officer Signature *Date* 10/28/2013

1. The service to be completed includes DNA testing for the common mutation (1226C>T) in the ACADVL gene in 1,000 Hawaii newborn screening bloodspot samples. This mutation causes very long chain acyl-CoA dehydrogenase deficiency (VLCADD). The state mandated Newborn Metabolic Screening Program includes testing for elevated levels of C14 on its panel, abormalities in which indicate VLCADD. DNA testing for VLCADD is not done as part of the initial state newborn screening. The national incidence of VLCADD is reported as 1/30,000 individuals. In Hawaii, however, the state Newborn Metabolic Screening Program has identified at least 13 children with at least one copy of the common mutation (1226C>T) since 2007. This is significantly higher than the reported national incidence. Interestingly, few of the children identified in Hawaii have clinical signs or symptoms, even though the 1226C>T mutation is classified as pathogenic (disease-causing). This quality improvement project will elucidate the incidence of 1226C>T mutations in a sample of 1000 Hawaii newborn screening bloodspots. Correlation of the incidence with clinical signs and symptoms will enable appropriate follow-up for identified newborns and their families. The information gained from DNA analysis is essential to providing management to newborns with a potentially significant metabolic condition. DNA testing through the Cincinnati Children's Hospital Medical Center (CCHMC) Molecular Genetics Laboratory will cost $2,288 for 1,000 newborn screening bloodspot samples. Results and interpretations will be available within 3 months of receipt of specimens in the laboratory.

6. There are two main reasons why it is neither practical nor advantageous for the department to procure a vendor by competitive means: Cincinnati Children's Hospital Medical Center (CCHMC) has the necessary experience to perform this specialized testing and is offering to complete the testing at cost. The Oregon State Public Health Laboratory currently performs newborn screening on Hawaii's bloodspot samples and uses the CCHMC Molecular Genetics Laboratory for follow-up DNA testing for VLCADD. As such, there is a professional relationship that already exists between those two entities and the collection and transfer of bloodspots from Oregon to Cincinnati will not provide a logistical or financial barrier. Physicians at CCHMC Molecular Genetics Laboratory are the authors of the VLCADD overview from the National Center for Biotechnology Information, a vetted source of accurate information about genetic conditions. They are considered experts on this particular condition and its molecular etiology. This laboratory has particular expertise testing for mutations in the ACADVL gene that cause very long chain acyl-CoA dehydrogenase deficiency. This laboratory is familiar with the results found in Hawaii, including the common 1226C>T mutation, due to the follow-up testing they currently complete for Hawaii's newborns. The CCHMC Molecular Genetics Laboratory is a College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) accredited molecular genetics laboratory. Given that this is a quality improvement activity for the Department of Health Genomics and Newborn Metabolic Screening Programs, the CCHMC laboratory has agreed to provide services at-cost, only charging for the cost of the test reagents. Neither the Hawaii state laboratory nor private laboratories in Hawaii perform DNA mutation analysis for VLCADD. It is neither practical nor advantageous to procure another vendor by competitive means because there is already an established relationship with CCHMC, they are willing to perform the testing at cost, and they have a documented expertise in this particular testing.

PE14-038D